

Life Sciences **Quality System Newletter** August 1999

This is OUR System

Did you know that there are Quality System procedures that cover...

Most of you know me as the SLO Branch Chief, but I've also been appointed by Ken Souza to be the SL Quality Manager. What does that mean? In a nutshell, I make sure the Quality System is working for us - we've got good training, the documents are useful, and the Corrective Action system is handling problems well. As part of this job, I have the invaluable support of SL Division and Branch management and Lockheed Martin Department management who help provide oversight of our Quality System through our Life Sciences Quality System Steering Committee.

 How to document hardware and experiment processes (tests, assembly steps, operations) AI-00007

You'll notice it's now the Life Sciences Quality System, and no longer the ISO Quality System. The reason for this is simple - we want the Quality

- How to operate the Low Vibration Rotational Device (LVRD) AI-04198 - Our newest procedure!
- System to be our system and useful to us, NOT something we're doing because the ISO auditors are coming. We've had procedures for years, because of our extensive mission interaction with MSFC, KSC,
- How the Division's Project Control Board operates SL-01.01

and JSC. But now our Quality System ties them all together, and makes them easily accessible on the web. Successful use of the Quality System and its procedures by SSBRP personnel will be a critical step to further validating and implementing the system.

ISO in Flight

Did You Know?

Remember, this is OUR system, if you find a problem, let us work together to fix it.

Duncan Atchison recently asked G. Lee Norbraten, Director of the ISO 9000 Office at JSC, "Will onboard (inflight) operations on either the shuttle or station be covered by ISO procedures?"

Paul "Tad" Savage Life Sciences Quality System Manager

Lee's reply: "The short answer is yes, in that all flight operations are within the scope of our Quality System. Configuration control of the flight data file, problem reporting (inflight anomaly (IFA) tracking), corrective action, records, training, etc., are all conducted consistently with Quality System (ISO 9001) requirements."

Audit Target Areas

"Flight hardware and experiments all follow the Quality System requirements for design, inspection, etc. In most cases, this did not require us to redefine processes or rewrite controlling documentation. That is, we did not write new ISO procedures if existing procedures met requirements."

Design Control, Product Traceability, and Calibration.



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Calibration in a Research Lab

Emily Holton, Richard Chase, 'Randa Hunter

Calibration is one of the areas the Auditors will focus on in November's audit. All laboratory Inspection Measuring & Test Equipment (IM&TE) must have one of the following four stickers attached:

"Calibrated" - The label will have a "Calibration Due Date" which is assigned by the Cal Lab. After this date expires, IM&TE must be recalibrated before use.

"Calibrated by User" - You must use an approved procedure to calibrate equipment. This procedure may be written, approved and controlled within the Document Control System, or be the Original Equipment Manufacturer's (OEM) Manual for the device. If you use a transfer standard to calibrate a device, it must have current calibration traceable to ANSI standards. You must keep a log or calibration record of any user calibration.

"Do not use until Calibrated" - You must submit a device with this label to the Cal Lab for calibration. If the device is user calibrated before use, it must be calibrated as stated above.

"Calibration not Required" - This determination is based on the test being conducted, and is made by the user. Equipment used for indication only must have one of these labels.

Note: Verification of accuracy for <u>Test Setup</u>, as determined by approved test procedures, must use calibrated IT&ME.

Further details are available in the Space Directorate's Calibration procedure 53.S.0011 and Ames procedure 53.ARC.0011.

Questions - contact Richard Chase (4-2916) or 'Randa Hunter at (4-2309).

Quality Term of the Month

Calibration - Set of operations which establishes, under specified conditions, the relationship between values indicated by a measuring device and the corresponding standard governing that measurement.

Upcoming Events

October 6 Internal Audits begin, details in next Newsletter.

September-October Refresher Training

Documentation Control

Last month we listed Peter Choi (4-6702) as the Document Change Coordinator. He's the point of contact for all Life Sciences Quality System document changes.

Christine McGann (4-2156) is the contact for SSBRP document changes; Twila Forbes (4-6809) is the contact for SL project level document changes.

QS Sites and Servers

ARC Quality System Main website:

http://dqa.arc.nasa.gov/iso9000/

Life Sciences Division website:

http://lifesci.arc.nasa.gov/QS/QS.html

SL Filer server:

Chooser/SL/N240A/SL FileServer

SSBRP Filer server:

Chooser/SF1/N244/Space Projects Server ETSC File server:

Chooser/SF/T20G/ETSC File Server

Suggestions/Comments

Duncan Atchison, Lockheed QS Lead (4-2144)